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## NOTICE OF ALLOWANCE AND FEE(S) DUE

51414

7590

04/08/2008

GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881

EXAMINER				
LIN, JERRY				
ART UNIT	PAPER NUMBER			
1631				

DATE MAILED: 04/08/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712.425	11/13/2003	Frank D. Lee	EPT-001C1	9956

TITLE OF INVENTION: PROTEOME EPITOPE TAGS AND METHODS OF USE THEREOF IN PROTEIN MODIFICATION ANALYSIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	07/08/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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## Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 51414 7590 04/08/2008 Certificate of Mailing or Transmission GOODWIN PROCTER LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/712.425 11/13/2003 Frank D. Lee EPT-001C1 9956 TITLE OF INVENTION: PROTEOME EPITOPE TAGS AND METHODS OF USE THEREOF IN PROTEIN MODIFICATION ANALYSIS APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$720 \$300 \$0 \$1020 07/08/2008 **EXAMINER** ART UNIT CLASS-SUBCLASS LIN, JERRY 1631 702-027000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PATENT ADMINISTRATOR			ART UNIT	PAPER NUMBER
EXCHANGE PLACE BOSTON, MA 02109-2881		1631 DATE MAILED: 04/08/200	8	

# **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 74 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 74 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)		
	10/712,425	LEE ET AL.		
Notice of Allowability	Examiner	Art Unit		
	Jerry Lin	1631		
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this app or other appropriate communication GHTS. This application is subject to	olication. If not included will be mailed in due course. <b>THIS</b>		
1. $\boxtimes$ This communication is responsive to <u>the amendments filed</u>	<u>December 14, 2007</u> .			
2. The allowed claim(s) is/are <u>1-10,12-14,16-20,22-25,31-35.</u>	<u>126,127 and 129-132</u> .			
<ul> <li>3.</li></ul>				
2. Certified copies of the priority documents have	been received in Application No			
3. Copies of the certified copies of the priority doc	cuments have been received in this i	national stage application from the		
International Bureau (PCT Rule 17.2(a)).				
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" on noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4. A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give	ENT of this application. itted. Note the attached EXAMINER	S AMENDMENT or NOTICE OF		
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	. , -			
<ul> <li>(a) ☐ including changes required by the Notice of Draftspers</li> </ul>		048) attached		
(a) ☐ including changes required by the Notice of Dranspers  1) ☐ hereto or 2) ☐ to Paper No./Mail Date	•	946) allached		
(b) ☐ including changes required by the attached Examiner's		office action of		
Paper No./Mail Date	s Amendment / Comment of in the C	office action of		
Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the				
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.				
Attachment(s)	5 Nation of Informal D	otant Application		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>D Notice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>	<ul><li>5. ☐ Notice of Informal P</li><li>6. ☐ Interview Summary</li></ul>	• •		
	Paper No./Mail Dat	e .		
<ol> <li>Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date</li> </ol>	7. 🔲 Examiner's Amendn	nent/Comment		
4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. 🛛 Examiner's Stateme	ent of Reasons for Allowance		
-	9.			

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The instant claims are drawn to a method for detecting the presence or absence of a post-translational modification at a location of a protein. This method is accomplished by first computationally predicting the fragments that will be produced after treating the protein and where the fragments contain at least one post translational modification site. In other words, the method first computationally creates a map of fragments of the protein and indicates which fragment has a post translational modification site. Secondly, the method creates the actual fragments and exposes to the fragments to capture agents bound to a support, where the capture agents that are specific to the fragments. Because the capture agents are specific to the fragments and bound to a support, the location of each fragment on the support is known. This creates a map of the fragments on the support. Finally, the bound fragments are exposed to a secondary capture agent that binds to the post-translational modification and the posttranslational modification is detected. Because the location of the fragments is known on the solid support, and because the location of the fragment is known on the protein from the computational steps, the claimed method can determine the location of the post-translational modification on the protein.

Gembitsky et al. (US 2005/0153298) is the closest prior art that teaches using a first capture agent that binds to a protein and a secondary capture agent that binds to a post-translational modification (page 5, paragraph 0046). However, Gembitsky et al. does not show the mapping of positions of post-translational modifications on a protein.

In contrast, the claimed subject matter maps the post-translational modification by two size-independent capture agents.

The prior art does contain teachings of computationally predicting fragments from a treatments, predicting the mass of the fragments (i.e. a theoretical digest), and then using mass spectrometry to detect if the actual mass of a fragments is different from the predicted mass. If the detected mass is different from the predicted mass, the fragment has a post-translational modification. (See Mann et al., page 263, right column- page 264). The method of using mass spectrometry to identify post-translational modifications measures the mass shift in a size dependent method. In contrast, the claimed subject matter uses capture agents in a size independent method. Thus, the computational measurements for the mass spectrometry method cannot be combined with capture agents because the capture agents and mass spectrometry rely on different principles.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6pm, M- Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/ /John S. Brusca/ Primary Examiner, Art Unit 1631